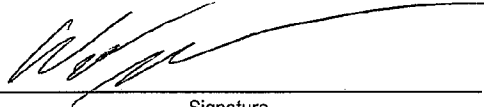


Doc Code: AP.PRE.REQ

PTO/SB/33 (07-05)

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PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional)	
		S63.2-7182-US02	
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	10/797996	3/11/2004	
	First Named Inventor Lixiao Wang		
	Art Unit	Examiner	
	1732	Matthew Daniels	
Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.			
This request is being filed with a notice of appeal.			
The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.			
I am the			
<input type="checkbox"/> applicant/inventor.		Signature	
<input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)		Walter J. Steinkraus	
		Typed or printed name	
<input checked="" type="checkbox"/> attorney or agent of record. 29592		952-563-3000	
Registration number _____		Telephone number	
<input type="checkbox"/> attorney or agent acting under 37 CFR 1.34.		November 16, 2007	
Registration number if acting under 37 CFR 1.34 _____		Date	
NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.			
<input type="checkbox"/> *Total of _____ forms are submitted.			

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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REASONS FOR PRE-APPEAL CONFERENCE

This is a response to the Advisory Action mailed September 19, 2007 wherein the Examiner has maintained the rejection of claims 18 and 23-26 under 35 U.S.C. §103(a) as being obvious over Crocker, U.S. Patent No. 5,843,116 in view of Gore, U.S. Patent No. 3,953,566 previously set forth in the Final Office Action mailed July 16, 2007.

Applicants disagree and submit that the reasoning employed in making the rejection is incorrect.

The dispute turns on whether or not Crocker's cross-linked polyethylene is different than the high density polyethylene recited in Applicant's independent claim 18 reproduced below:

A method of forming a balloon comprising at least three layers comprising the steps of:

- i) providing first, second and third tubes, the second tube formed of a tube made of a material selected from the group consisting of fluoropolymers and high density polyethylene;
- ii) inserting the first tube into the second tube;
- iii) inserting the second tube into the third tube;
- iv) inserting the first, second and third tubes into a balloon mold;
- v) expanding the first, second and third tubes at a desired temperature so as to form a balloon.

Applicants have argued in the last two responses and continue to maintain that the cross-linked polyethylene disclosed by Crocker et al. is different than high density polyethylene, and that cross-linked polyethylene is a polyethylene that has been subsequently modified by linking its molecules in a manner which changes the material from a thermoplastic to a thermoset.

There is no dispute as to Crocker et al.'s silence as to a second tube made from fluoropolymers or high density polyethylene. See Final Office Action, 7/16/2007, page 3, first full paragraph.

However, the Examiner has taken the position that "Crocker clearly suggests cross-linked polyethylene (5:35-39), and...crosslinking would produce a

polyethylene having “high density”, as claimed.” Final Office Action, 7/16/2007, page 3, second full paragraph.

Even if true that crosslinking of a polyethylene produces a higher density for the particular polyethylene that is being crosslinked, Applicants’ maintain that the term “high density polyethylene” as employed in the present application is a term that is understood by those of ordinary skill in the art term to refer to a *thermoplastic* polyethylene, and not to thermoset, i.e crosslinked, polyethylene as disclosed by Crocker et al., nor would the two behave equivalently or exhibit the same properties. They simply are not equivalent materials.

In the Advisory Action it is stated that “[a]s set forth previously, the term “high density” is not differentiated in the specification by any material characteristics and it is submitted that the references would provide high density polyethylene.”

This is incorrect. Applicants have differentiated the polyethylene simply by the use of the term “high density”, for example, as opposed to “low density”, “linear low density”, “medium density”, or “crosslinked” polyethylene. ***As is notoriously well known***, each of these terms has a specific meaning to those of ordinary skill in the art, each referring to a different polyethylene material having different characteristics. See attached MatWeb overview of high density polyethylene clearly illustrating it is understood to be thermoplastic, not thermoset.

The Examiner, in the Final Office Action mailed July 16, 2007, found these arguments not persuasive for the following reasons:

Applicants’ position rests on the use of a relative term which is not differentiated in the specification by any material characteristics. Therefore, it is submitted that the reference provides a “high density” polyethylene, or that a high density polyethylene is produced as a result of crosslinking, and that the rejection based thereon is valid. It is submitted that it is not implicit that high density polyethylene is thermoplastic (or remains a thermoplastic material), as asserted by Applicants’ arguments.. See, for example, USPN 3376238 to Gregorian, which teaches providing a commercially available polyethylene, and crosslinking, providing a crosslinked high density polyethylene (7:15-25, also see Example 1). Therefore, the asserted thermoplastic nature of the high density polyethylene, which does not appear to be supported by the specification and is not commensurate with the scope of the claim, is not sufficient to distinguish the claimed invention.

Final Office Action, pages 5-6, section 6.

Applicants' submit, however, that Gregorian supports Applicants' position, rather than being contrary to it. Gregorian starts with a thermoplastic polyethylene that is already high density polyethylene (0.96 g/cc). Gregorian then crosslinks and treats with acid to produce a different material namely "crosslinked, microporous, high density polyethylene." Any person of skill in the art recognizes that the crosslinked material is no longer the same as the material known in the art as "high density polyethylene."

Even more to the point, it is clear from Gregorian taken with the Matweb Overview, that the "high density" characterization in Gregorian's Example 2 comes from the fact that the *starting material* is high density polyethylene, not because of the crosslinking. Consequently Gregorian provides no support for the incorrect assertion that Crocker's polyethylene is high density because it is crosslinked. There is thus nothing in the record of this case that supports the Examiner's assertion that Crocker's polyethylene is "high density polyethylene."

Thus, crosslinking is not an inherent characteristic of high density polyethylene.

It was further asserted in the Final Office Action that "...in the alternative, Gore teaches a PTFE (a fluoropolymer) tubular product (14: 17-20) having a dense structure and extremely high strength which would have been suitable for use in Crocker's method as the expansion limiting bands (Crocker, 5:28-30)." Final Office Action, July 16, 2007, page 3.

Again, Applicants disagree.

First of all, it is incorrect to describe the PTFE disclosed by Gore as having a dense structure. In fact, to the contrary, Gore describes the PTFE disclosed therein, as "a tetrafluoroethylene polymer in porous form which has an amorphous content exceeding about 5% and which has a micro-structure characterized by nodes interconnected by fibrils." Gore, US 3,953,566, Abstract. An alternative description for this material is expanded PTFE. See, for example, Gore, column 5, lines 47-58.

Clearly, Gore describes the material as being "porous" and not "dense" as asserted in the Final Office Action.

There is nothing in Crocker et al. that would lead one of skill in the art to employ the porous PTFE of Gore for forming the expansion limiting bands 40, 44 of Crocker et al.

Crocker et al.'s expansion limiting bands are described as being "nondistensible". See col. 5, lines 32-36. One way to provide the desired "expansion limiting characteristics" is to form the expansion limiting bands 40, 44 from nondistensible materials. One example is polyester. See col. 5, lines 32-36. Examples of other generally nondistensible materials given by Crocker et al. include "...nylon, polyamide, Kevlar fiber, cross-linked polyethylene, polyethylene terephthalate..."

There is nothing in Crocker et al. that would lead one of ordinary skill in the art to substitute Gore's PTFE with its porous, node and fibril structure, for the inelastic, nondistensible materials with the specific expansion limiting characteristics desired by Crocker et al. Furthermore, Gore fails to describe the porous PTFE material disclosed therein as being either inelastic or nondistensible.

Crocker et al. provides no basis for selecting any porous material, particularly porous PTFE, and one of ordinary skill in the art would not be lead to conclude that the porous PTFE material having a node and fibril structure as disclosed by Gore would indeed be a suitable substitute for the materials disclosed for use in forming the expansion limiting bands disclosed by Crocker et al.

Under *KSR*, one of ordinary skill in the art must not only be able to implement a predictable variation, one must readily recognize a benefit to doing so. There is simply nothing to suggest that there would be a benefit to making the expansion limiting bands of Crocker et al. with porous PTFE disclosed by Gore, not without using impermissible hindsight reconstruction, using Applicants' own invention. If one of skill in the art cannot implement a predictable variation, or see the benefit of doing so, the combination does not preclude patentability under 35 U.S.C. §103(a). See *KSR International v. Teleflex Inc.*, U.S. Supreme Court No. 04-1350 (April 30, 2007). Applicants submit that the benefit in making this combination is not readily apparent, and that claim 18 is therefore not rendered obvious over Crocker et al. in view of Gore.

Hindsight reconstruction is impermissible. In making a rejection, it is simply not good enough to pick and choose elements randomly from prior art references.

Even after KSR, there must be some motivation to combine the references. “The TSM test captures a helpful insight: A patent composed of several elements is not proved obvious merely by demonstrating that each element was, independently, known in the prior art.” *KSR International v. Teleflex Inc.*, U.S. Supreme Court No. 04-1350 (April 30, 2007).

For these reasons, claim 18 is not obvious over Crocker et al. in view of Gore.

Independent claim 23 also recites, among other features, “...providing first, second and third tubes, the second tube formed of expanded PTFE....”

Claim 23 is not obvious over the combination of Crocker et al. and Gore for at least the reasons that claim 18 is not obvious over the combination. Claims 24-26 depend from claim 23 and are not obvious over this combination for at least the reasons that claims 18 and 23 are not obvious over this combination.

Reversal of this rejection is respectfully requested.

Respectfully Submitted,
Vidas, Arrett & Steinkraus, P.A.

Date: November 16, 2007

By /Walter J. Steinkraus/
Walter J. Steinkraus
Registration No.: 29592

MatWeb, The Online Materials Database**Overview - High Density Polyethylene (HDPE), Extruded****Subcategory:** HDPE; Polyethylene; Polymer; Thermoplastic**Close Analogs:**

Click button for specific proprietary grades that belong to this Overview class.

Proprietary Grades

Please be aware that some proprietary polymers may not be listed because they fall into more than one class or because of ambiguity in manufacturer's information.

Key Words: Plastics, Polymers

The property data has been taken from proprietary materials in the MatWeb database. Each property value reported is the average of appropriate MatWeb entries and the comments report the maximum, minimum, and number of data points used to calculate the value. The values are not necessarily typical of any specific grade, especially less common values and those that can be most affected by additives or processing methods.

Physical Properties	Metric	English	Comments
Density	0.936 - 0.962 g/cc	0.0338 - 0.0348 lb/in ³	Average = 0.948 g/cc; Grade Count = 21
Apparent Bulk Density	0.58 - 0.61 g/cc	0.021 - 0.022 lb/in ³	Average = 0.59 g/cc; Grade Count=4
Water Absorption	0.01 %	0.01 %	Grade Count = 1
Moisture Vapor Transmission	0.38 cc-mm/m ² -24hr-atm	0.965 cc-mil/100 in ² -24hr-atm	Grade Count = 1
Environmental Stress Crack Resistance	10 - 5000 hour	10 - 5000 hour	Average = 1600 hr; Grade Count = 16
Melt Flow	0.14 - 13 g/10 min	0.14 - 13 g/10 min	Average = 3.6 g/10 min; Grade Count = 21
Mechanical Properties			
Hardness, Shore D	58 - 65	58 - 65	Average = 62; Grade Count = 14
Tensile Strength, Ultimate	24 - 45 MPa	3480 - 6530 psi	Average = 30 MPa; Grade Count = 9

Tensile Strength, Yield	15 - 30 MPa	2180 - 4350 psi	Average = 21.9 MPa; Grade Count = 15
Elongation at Break	500 - 1000 %	500 - 1000 %	Average = 840%; Grade Count = 17
Tensile Modulus	0.8 - 0.99 GPa	116 - 144 ksi	Average = 0.86 GPa; Grade Count = 3
Flexural Modulus	0.5 - 1.52 GPa	72.5 - 220 ksi	Average = 0.928 GPa; Grade Count = 16
Izod Impact, Notched	0.8 - 7.5 J/cm	1.5 - 14.1 ft-lb/in	Average = 3.7 J/cm; Grade Count = 6
Tensile Impact Strength	320 - 480 kJ/m ²	152 - 228 ft-lb/in ²	Average = 380 kJ/m ² ; Grade Count = 3
Coefficient of Friction	0.28	0.28	Grade Count=1

Electrical Properties

Electrical Resistivity	1e+017 ohm-cm	1e+017 ohm-cm	Grade Count = 2
Surface Resistance	1e+017 ohm	1e+017 ohm	Grade Count = 1
Dielectric Constant	2.3	2.3	Grade Count = 2
Dissipation Factor	0.0001 - 0.0005	0.0001 - 0.0005	Average = 0.0003; Grade Count = 2

Thermal Properties

CTE, linear 20°C	140 µm/m-°C	77.8 µin/in-°F	Grade Count=3
Melting Point	124 - 131 °C	255 - 268 °F	Average = 130°C; Grade Count = 9
Vicat Softening Point	108 - 129 °C	226 - 264 °F	Average = 120°C; Grade Count = 15

Brittleness Temperature	-100 - -70 °C	-148 - -94 °F	Average = -86.2°C; Grade Count=16
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Processing Properties

Processing Temperature	180 - 315 °C	356 - 599 °F	Average = 210°C; Grade Count = 17
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